

REMARKS/ARGUMENTS

The Office Action mailed June 15, 2004 has been carefully reviewed. Reconsideration of this application, as amended and in view of the following remarks, is respectfully requested.

Claims 7, 13, 23-27, and 29-31 were withdrawn from consideration in this application. In response to a Requirement to Elect a Species in the Office Action mailed July 18, 2002, claims 7, 13, 23-26, and 29-31 were withdrawn from consideration. In the Office Action mailed December 5, 2002 claim 27 was indicated to be dependent upon non-elected claim 26 and therefore claim 27 was indicated to be non-elected.

The claims presented for examination in this application are: claims 2-6, 8-12, 14-22, 28, and 32-35.

35 USC 112 Rejection – Claim 2

In numbered paragraph 4 of the Office Action mailed June 15, 2004 claim 2 was rejected under 35 USC 112 as having insufficient antecedent basis for the term “said portion.” Claim 2 has been amended and the term “said portion” has been changed to “said first unit.” Applicants submit that there is sufficient antecedent basis for the term “said first unit.”

35 USC 112 Rejection – Claim 11

In numbered paragraph 5 of the Office Action mailed June 15, 2004 claim 11 was rejected under 35 USC 112 as having insufficient antecedent basis for the term “said device.” Claim 11 has been amended and Applicants submit that there is now sufficient antecedent basis for the term “said device.”

35 USC 102 Rejection

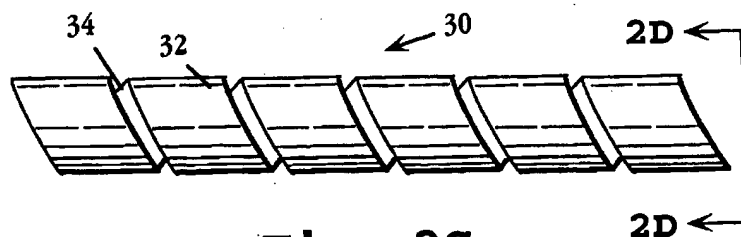
In numbered paragraph 6 of the Office Action mailed June 15, 2004 claims 2-5 and 8-10 were rejected under 35 USC 102 (b) as allegedly being anticipated by the Phan et al reference (US Patent No. 5, 674,242).

Applicant has amended claims 2-5 and 8-10 presented for examination; therefore claims 2-5 and 8-10 are now presented in amended form. Since claims 2-5 and 8-10 now appear in amended form the 35 USC §102(b) rejection in the Office Action mailed June 15, 2004 no longer applies.

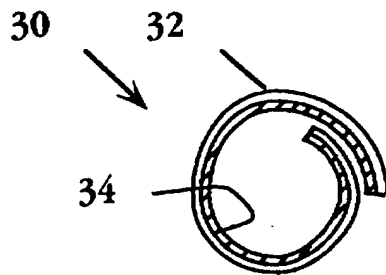
#### The Phan et al Reference Device

The Phan et al reference discloses a drug-delivery endoprosthesis device for insertion at a vessel target site via catheter placement at the site. The Phan et al reference device comprises a shape-memory polymer member 32 and a structural member composed of a shape-memory alloy 34. The Phan et al reference device expands upon activation as stated in the Phan et al reference, "The members are cooled below their critical temperatures to secure the device in its small-diameter, contracted configuration. Upon activation of the material transition, the coextensive members coexpand toward their memory conditions, to a larger-diameter state." (Col. 4, lines 56-61)

The Phan et al reference device is illustrated in figures FIG. 2C and FIG. 2D set out below and described in the Phan et al reference sections out below.



**Fig. 2C**



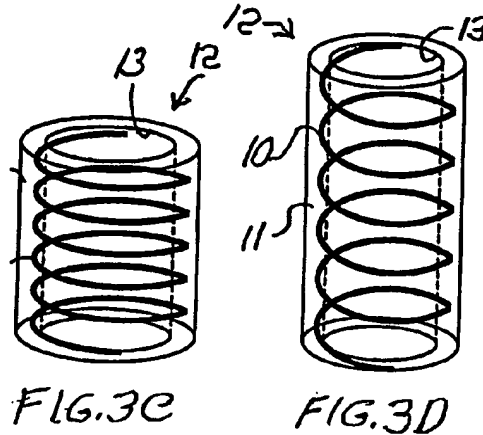
**Fig. 2D**

With reference to FIG. 2A, an endoprosthesis device 30 composed of a shape-memory polymer member 32 and a structural member 34 is shown. In this embodiment, the members are each composed of a shape-memory material, for example, the structural member is composed of a shape-memory alloy and the polymer member is composed of a shape-memory polymer. (Col. 4, lines 31-37)

In a preferred embodiment, the members are both formed of a shape-memory material and are placed into a coextensive, small-diameter, contracted state, shown in FIG. 2B, by activating the material transition, e.g., warming the shape-memory material to above its critical temperature, and winding the members together around a balloon catheter. The members are cooled below their critical temperatures to secure the device in its small-diameter, contracted configuration.

Upon activation of the material transition, the coextensive members coexpand toward their memory conditions, to a larger-diameter state, as shown in FIG. 2C. (Col. 4, lines 50-61)

Applicants invention provides a catheter having a shape memory polymer comprised of a cylinder 11 and a shape memory alloy spring 10 as illustrated in figures FIG. 3C and FIG. 3D of Applicants' published United States Patent Application No 2002/0142119 published October 3, 2002. Upon activation by a change in temperature, Applicants' shape memory alloy spring 10 extends the structure 12 causing a radial contraction and stretching the shape memory polymer cylinder 11. This is described in paragraph [0064] of Applicants' published patent application set out below.



[0064] The composite of Figures 3A-3D shows in Figure 3A an extended or stretched SMA spring 10, in Figure 3B, the SMA spring 10 is compressed or deformed with an SMP tube 11 molded around it and cooled to ambient temperature to produce a structure 12 with an opening 13; in Figure 3C, the composite structure 12 is shown after the SMP tube 11 cures allowing the structure 12 to come to an equilibrium. When both the SMA spring 10 and the SMP tube 11 are heated above their transformation temperatures, the SMA spring 10 extends the structure 12 causing a radial contraction and stretching the SMP tube 11 as seen in Figure 3D. When the structure 12 is then heated above the SMP transition temperature but below the SMA transformation temperature, the SMP tube 11 will pull back toward its as-molded shape and compress the ductile SMA spring 10 and reverse to that of Figure 3C.

Applicant respectfully submits that the Phan et al reference does not show the structural elements of the claims now presented for examination. For example, the following structural elements of amended claims 2-5 and 8-10 are not found in the Phan et al reference: "said second unit comprising said second structure including said shape memory polymer comprising a cylinder, wherein said first unit is positioned in said second unit such that changes in temperature of said shape memory alloy causes said first unit to change position by a radial contraction and a longitudinal extension and to stretch said second unit

comprising said second structure including said shape memory polymer along said longitudinal axis.”

As stated in Verdegaal Bros. v. Union Oil Co. of California, 814 F.2<sup>nd</sup> 628, 631 USPQ 1051, 1053 (Fed. Cir. 1987), “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference.” Since structural elements of amended claims 2-5 and 8-10 now presented for examination are not shown by the Phan et al reference, the rejection is unsupported by the art and should be withdrawn.

35 USC 103 Rejection - Phan et al in view of Maynard

In numbered paragraph 7 of the Office Action mailed June 15, 2004, claims 11-12, 14-22, 28, and 34-35 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Phan et al in view of Maynard (US Patent No. 5,405,337).

Applicants have amended all of the independent claims and some of the dependent claims in the subject application. Applicant respectfully traverses the rejection of claims 11-12, 14-22, 28, and 34-35 under 35 U.S.C. §103.

The Phan et al reference does not show the structural elements of claims 11-12, 14-22, 28, and 34-35 identified above. The Maynard reference does not show the missing elements. Further, there is no suggestion in the references to form a proper combination of the Phan et al and Maynard references to meet Applicants claimed invention.

There could be no obvious modification of the Phan et al to meet Applicants claimed invention because the Phan et al reference device expands upon activation as stated in the Phan et al reference, “The members are cooled below their critical temperatures to secure the device in its small-diameter, contracted configuration. Upon activation of the material transition, the coextensive members coexpand toward their memory conditions, to a larger-diameter state.” (Col. 4, lines 56-61)

This is contrasted with Applicants claimed invention wherein “changes in temperature of said shape memory alloy causes said first structure to change position by a radial contraction and a longitudinal extension and to stretch said second structure along said longitudinal axis.” The Phan et al reference device expands to release a balloon catheter. To modify the Phan et al reference device to produce a “radial contraction” according to Applicants’ claim would defeat the operation and purpose of the Phan et al reference device.

35 USC 103 Rejection - Phan et al and Maynard in view of Lee et al

In numbered paragraph 8 of the Office Action mailed June 15, 2004, claims 32-33 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Phan et al and Maynard in view of Lee et al (US Patent No. 6,059,815). Applicant respectfully traverses the rejection of claims 32-33 under 35 U.S.C. §103.

The Phan et al reference does not show the structural elements of claims 32-33. The Maynard reference does not show the missing elements. The Lee et al reference does not show the missing elements.

Further, there is no suggestion in the references to form a proper combination of the Phan et al and Maynard and Lee et al references to meet Applicants claimed invention.

There could be no obvious modification of the Phan et al to meet Applicants claimed invention because the Phan et al reference device expands upon activation as stated in the Phan et al reference, “The members are cooled below their critical temperatures to secure the device in its small-diameter, contracted configuration. Upon activation of the material transition, the coextensive members coexpand toward their memory conditions, to a larger-diameter state.” (Col. 4, lines 56-61)

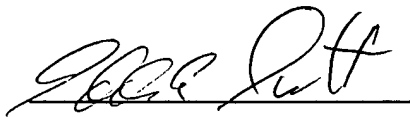
This is contrasted with Applicants claimed invention wherein “changes in temperature of said shape memory alloy causes said first portion of said

articulated tip with said composite of shape memory alloy to change position by a radial contraction and a longitudinal extension and to stretch said second portion of said articulated along said central axis.” The Phan et al reference device expands to release a balloon catheter. To modify the Phan et al reference device to produce a “radial contraction” according to Applicants’ claim would defeat the operation and purpose of the Phan et al reference device.

SUMMARY

The undersigned respectfully submits that, in view of the foregoing amendments and the foregoing remarks, the rejections of the claims raised in the Office Action dated June 15, 2004 have been fully addressed and overcome. The present application is believed to be in condition for allowance. It is respectfully requested that this application be reconsidered, that the claims be allowed, and that this case be passed to issue. If it is believed that a telephone conversation would expedite the prosecution of the present application, or clarify matters with regard to its allowance, the Examiner is invited to call the undersigned attorney at (925) 424-6897.

Respectfully submitted,



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